

REMARKS

Applicant acknowledges receipt of the Office Action mailed November 16, 2009.

In the Office Action¹, the Examiner objected to the drawings; rejected claim 1 under 35 U.S.C. § 112, second paragraph; rejected claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Harms et al.* ("*Harms*") (U.S. Patent No. 5,364,385) in view of *Goldhaber* (U.S. Patent No. 4,396,382); and rejected claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Matthews* (GB Patent No. 2080116) in view of *Goldhaber*.

By this Reply, Applicant amends FIGs. 1-3, and amends claims 1, 6, 9, 10, 14, 15, 19, 22, 25, 28-30, 32, 36, and 39. Claims 1-39 are currently pending. Claim 1 is the only pending independent claim.

The originally-filed specification, claims, abstract, and drawings fully support the amendments to FIGs. 1-3 and amended claims 1, 6, 9, 10, 14, 15, 19, 22, 25, 28-30, 32, 36, and 39. No new matter has been introduced.

Applicant traverses the objection and rejections above and respectfully requests reconsideration for at least the reasons that follow.

I. OBJECTION TO THE DRAWINGS

The drawings stand objected to as allegedly failing to comply with MPEP §608.02(g), as Figures 1-3 should be designated by a legend such as -- Prior Art -- because only that which is old is illustrated. (*Office Action*, p. 2, para. 1). Applicant submits that the objection to the drawings has been rendered moot by the amendments

¹ The Office Action contains a number of statements reflecting characterizations of the related art and the claims. Regardless of whether any such statement is identified herein, Applicant declines to automatically subscribe to any statement or characterization in the Office Action.

to FIGs. 1-3. Specifically, Applicant has added a "Prior Art" legend to FIGs. 1-3. Applicant therefore requests that the objection to the drawings be withdrawn.

II. 35 U.S.C. § 112, SECOND PARAGRAPH, REJECTION

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner contends that, "[i]n claim 1, Applicant claims that the fluid bag comprises one compartment or a combination of different compartments. The claiming of limitations in the alternative renders the claim unclear, since it is not clear which of the elements defines the invention." (*Office Action*, p. 2, para. 3). The Examiner further contends that, "Applicant sets forth that the fluid bag is sized to contain a certain quantity of fluid q , and further defines the capacity of the bag as $q \geq 2000$. However, Applicant fails to set forth in the claim what quantity q represents . . ." (*Id.* at p. 3, para. 4). Applicant submits that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, has been rendered moot by the amendments to claim 1. Applicant therefore requests that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, be withdrawn.

III. 35 U.S.C. § 103(a) REJECTIONS

Applicant traverses the rejection of claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Harms* in view of *Goldhaber*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that amended independent claim 1 patentably distinguishes over *Harms* and *Goldhaber* at least for the reasons described below.

The key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. See M.P.E.P. § 2142, 8th Ed., Rev. 7 (July 2008). Such an analysis should be made explicit and cannot be premised upon mere conclusory statements. See *id.* “A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention.” M.P.E.P. § 2145. Furthermore, “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art” at the time the invention was made. M.P.E.P. § 2143.01(III), internal citation omitted. Moreover, “[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.” M.P.E.P. § 2141.02(I), internal citations omitted (emphasis in original).

“[T]he framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). . . . The factual inquiries . . . [include determining the scope and content of the prior art and] . . . [a]scertaining the differences between the claimed invention and the prior art.” M.P.E.P. § 2141(II). “Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.” M.P.E.P. § 2141(III).

Amended independent claim 1 recites a fluid bag comprising one or more compartments, each compartment suitable for containing one or more fluids, the fluid

bag containing, in at least one compartment, a fluid selected from a group consisting of: "a dialysis fluid for use in an apparatus for hemodialysis, hemodiafiltration, hemofiltration, or peritoneal dialysis; a replacement fluid to be delivered to a patient in order to replace an ultrafiltrate withdrawn from a patient during hemodialysis, hemofiltration, hemodiafiltration, or peritoneal dialysis; and a rest product fluid from a process of hemodialysis, hemofiltration, hemodiafiltration, or peritoneal dialysis, . . . said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, a distance between said first and second sheets defining a thickness (t) of the fluid bag, said fluid bag being sized to contain at least a certain quantity (q), in ml, of fluid . . . , wherein said thickness (t) of the fluid bag . . . never exceeds a certain value (v), in mm, wherein: $q \geq 2000$, and $v \leq 2q/100$."

Harms appears to disclose a bag disclosed for the collection, freezing, storage, and rapid thawing of fluids, and particularly blood and blood components. Front and back sheets of fluid impervious material are bonded to one another along edge portions thereof to form a bag defining a reservoir. The front and back sheets are further bonded together at a plurality of locations intermediate the edge portions to constrain the distance by which the front and back sheets can separate. A port is provided for introducing and discharging fluid into and out of the reservoir. (*Harms*, Abstract).

Applicant points out that the Examiner concedes that "Harms fails to disclose the exact volume to thickness ratio." (*Office Action*, p. 3, para. 6). The Examiner further contends, however, that "[i]t has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural

limitations." (*Id.* at pp. 3-4, para. 6). Applicant respectfully disagrees with the Examiner's mischaracterization of the claim. With respect to the volume to thickness ratio, amended independent claim 1 recites, *inter alia*, "said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, a distance between said first and second sheets defining a thickness (t) of the fluid bag, said fluid bag being sized to contain at least a certain quantity (q), in ml, of fluid when the fluid bag is completely filled with the one or more fluids, wherein said thickness (t) of the fluid bag, when the fluid bag is configured to hang suspended in a vertical direction, never exceeds a certain value (v), in mm, wherein: $q \geq 2000$, and $v \leq 2q/100$." Such limitation is not directed to "the manner in which [the] claimed apparatus is intended to be employed." Rather, the limitation recited above is a structural limitation that must be given due weight when examining amended independent claim 1. Further, the specification of the present application recites several advantages of the fluid bag having the volume to thickness ratio discussed above. For example, as disclosed on page 4, lines 22-36 of the specification,

[t]he fluid bag is sufficiently large, such that it can contain an appropriate amount of fluid, for example of a dialysis fluid, even if this fluid is not in a concentrated form. It is therefore not necessary to exchange the fluid bag so often. Furthermore, the fluid bag is arranged such that it is not too thick. It is thereby possible to easily arrange a plurality of fluid bags next to each other in connection with an apparatus . . . It is thereby not necessary to supply the apparatus with new fluid bags so often. This is advantageous since it makes it possible for . . . example a nurse to administer the work involved with the supply of fluid bags in an efficient manner. Furthermore, because of the . . . defined relationship between volume and thickness, the fluid bags according to the invention are easy to handle.

Harms, in fact, teaches away from a fluid bag having a relatively large volume of dialysis fluid, e.g., $q \geq 2000$ ml. As disclosed in column 1, lines 21-24 of *Harms*, "[t]ypically, plasma and whole blood are frozen within six hours after collection, in polyvinyl chloride bags holding about 300 milliliters" (emphasis added).

In addition, the Examiner further concedes that "Harms discloses that the bag contains blood products, not dialysis fluids as claimed by Applicant" (emphasis added). (*Id.* at p. 4, ll. 2-3).

In order to cure the deficiencies of *Harms*, the Examiner relies on *Goldhaber* and contends that "Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid." (*Office Action*, p. 4, ll. 3-4).

Goldhaber appears to disclose "a solution bag formed of three plastic walls sealed together about their peripheries to define a pair of separate chambers for peritoneal dialysis and the like." (*Goldhaber*, Abstract). *Goldhaber*, however, fails to teach or suggest at least a fluid bag comprising one or more compartments, each compartment suitable for containing one or more fluids, . . . "said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, a distance between said first and second sheets defining a thickness (t) of the fluid bag, said fluid bag being sized to contain at least a certain quantity (q), in ml, of fluid . . . , wherein said thickness (t) of the fluid bag . . . never exceeds a certain value (v), in mm, wherein: $q \geq 2000$, and $v \leq 2q/100$ " (emphasis added), as recited in amended independent claim 1.

As explained above, the elements of amended independent claim 1 are neither taught nor suggested by the cited references. Consequently, in the Office Action the

Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 1 and this claim is allowable over the cited references. Claims 2-39 are also allowable over *Harms* and *Goldhaber*, due at least to their dependence from allowable independent claim 1, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 1-39 under 35 U.S.C. § 103(a) be withdrawn.

Applicant also traverses the rejection of claims 1-39 under 35 U.S.C. § 103(a) as being unpatentable over *Matthews* in view of *Goldhaber*. Applicant respectfully disagrees with the Examiner's arguments and conclusions and submits that independent claim 1 patentably distinguishes over *Matthews* and *Goldhaber* at least for the reasons described below.

As discussed above, independent claim 1 recites a fluid bag comprising one or more compartments, each compartment being suitable for containing one or more fluids, the fluid bag containing, in at least one compartment, a fluid selected from a group consisting of: "a dialysis fluid for use in an apparatus for hemodialysis, hemodiafiltration, hemofiltration, or peritoneal dialysis; a replacement fluid to be delivered to a patient in order to replace an ultrafiltrate withdrawn from a patient during hemodialysis, hemofiltration, hemodiafiltration, or peritoneal dialysis; and a rest product fluid from a process of hemodialysis, hemofiltration, hemodiafiltration, or peritoneal

dialysis, . . . said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, a distance between said first and second sheets defining a thickness (t) of the fluid bag, said fluid bag being sized to contain at least a certain quantity (q), in ml, of fluid . . . , wherein said thickness (t) of the fluid bag . . . never exceeds a certain value (v), in mm, wherein: $q \geq 2000$, and $v \leq 2q/100$."

Matthews appears to disclose a drainage bag for wear as a urine collection bag. The bag has front and rear walls 10, 12 of plastic material welded together to form a peripheral seam 16. The front and rear walls are further joined together by closed loop welds 20 inside the area enclosed by the peripheral seam. The bag preferably has 3-10 closed loop welds. These welds prevent bulging of the bag when it is full of liquid. (*Matthews*, Abstract).

The Examiner concedes, however, that "Matthews fails to disclose the exact volume to thickness ratio." (*Office Action*, p. 7, line 1). The Examiner further contends that "[i]t has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations." (*Id.* at p. 7, ll. 1-4). At least for the reasons discussed above, Applicant respectfully disagrees with the Examiner's characterization of the claimed volume to thickness ratio limitation in amended independent claim 1.

Matthews also teaches away from a fluid bag having a relatively large volume of dialysis fluid, e.g., $q \geq 2000$ ml. As disclosed in column 1, lines 15-18 of *Matthews*, "[f]rom the point of view of concealment on a wearer, it is greatly preferable if the bag

when full is relatively flat so it can remain unnoticed beneath clothing" (emphases added).

The Examiner further concedes that "Matthews discloses that the bag contains waste products, not dialysis fluids as claimed by Applicant." (*Id.* at p. 7, ll. 5-6).

In order to cure the deficiencies of *Matthews*, the Examiner relies on *Goldhaber* and contends that "Goldhaber discloses a flexible bag that may contain fresh and spent dialysis fluid." (*Office Action*, p. 7, ll. 6-7).

As discussed above, *Goldhaber* appears to disclose "a solution bag formed of three plastic walls sealed together about their peripheries to define a pair of separate chambers for peritoneal dialysis and the like." (*Goldhaber*, Abstract). *Goldhaber*, however, fails to teach or suggest at least a fluid bag comprising one or more compartments, each compartment suitable for containing one or more fluids, . . . "said fluid bag having a first main sheet and a second main sheet configured opposite to said first main sheet, a distance between said first and second sheets defining a thickness (t) of the fluid bag, said fluid bag being sized to contain at least a certain quantity (q), in ml, of fluid . . . , wherein said thickness (t) of the fluid bag . . . never exceeds a certain value (v), in mm, wherein: $q \geq 2000$, and $v \leq 2q/100$ " (emphasis added), as recited in amended independent claim 1.

As explained above, the elements of amended independent claim 1 are neither taught nor suggested by the cited references. Consequently, in the Office Action the Examiner has neither properly determined the scope and content of the prior art, nor properly ascertained the differences between the prior art and the claim. Accordingly, no sufficient reason has been clearly articulated as to why the claim would have been

obvious to one of ordinary skill in view of the prior art. Therefore, a *prima facie* case of obviousness has not been established for independent claim 1 and this claim is allowable over the cited references. Claims 2-39 are also allowable over *Matthews* and *Goldhaber*, due at least to their dependence from allowable independent claim 1, and due to their additional recitations of novel subject matter. Applicant therefore requests that the rejection of claims 1-39 under 35 U.S.C. § 103(a) be withdrawn.

IV. CONCLUSION

Applicant respectfully submits that claims 1-39 are in condition for allowance.

In view of the foregoing, Applicant respectfully requests reconsideration and reexamination of this application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: February 16, 2010

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Attachment: One (1) Replacement Sheet (1/3) - amended FIGs. 1-3